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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 456,278	12/07/1999	Jesus Miranda	99.FIT-07.US	6233

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EXAMINER

GHALL, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/456,278

Applicant(s)

MIRANDA ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5 and 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment A, both filed 3/26/2002.

Claim 27 has been added per applicants' amendment A, in Paper No. 9.

This application contains claims 2, 4, 5, 8-26 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 3, 6, 7, and 27 are included in the prosecution.

Applicants' arguments are moot in view of the following new ground of rejection as necessitated by applicants' amendment A:

Claim Objections

1. Claim 1 is objected to because of the following informalities: the marked copy of the claims' amendment does not show the same changes as the clean copy.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,165,497 ('497).

Applicants' amended claims 1 and 27 read as follows:

A transdermal patch comprising the following layers:

- An impermeable backing layer,
- Silicone adhesive layer containing the drug,
- Acrylic adhesive layer, and
- Removable release liner.

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US '497 disclosed a rate-controlled nicotine (volatile drug) delivery system comprising:

- An impermeable backing,
- Nicotine reservoir,
- Nicotine release controlling membrane, and
- A release liner. (Abstract; col.2, lines 58-61; col.3, lines 30-37).

The device delivers nicotine in an amount of 0.2 to 4.0 mg/hr (col.5, line 27-29). The rate-controlling membrane comprises vinyl acetate copolymer (acrylate adhesive) and the reservoir comprises silicone adhesive and nicotine (col. 7, lines 1-4, 28-30).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 6, 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '497, US 5,603,947 ('947) or US 5,298,257 ('257) each standing by it self or in combination with US 5,316,759 ('759) as applied to claim 3, or US 5,721,257 ('257) as applied to claim 6.

The teachings of US '497 are discussed under 102 rejection above. However, the reference does not teach the drug as a combination of nicotine and mecamylamine, or the siliconized release liner.

It is well known in the art to treat addiction or drug dependency by administering the drug and its antagonist. The siliconized release liner is also well known in the art.

US '947 discloses a device for providing nicotine replacement therapy transdermally. The device comprises an impermeable backing, matrix layer containing nicotine and silicones, an adhesive layer to affix the device to the skin and a release liner (abstract; col.2, lines 16-20; col.3, lines 15-18; col.5, lines 51-53; col.6, lines 1-8, 40-45).

US '257 teaches a percutaneous preparation for administering nicotine that can be in the form of a solid patch (abstract; col.8, lines 23-26). The preparation comprises nicotine and silicones (col.3, lines 41-45, 55-60; col.4, lines 20-21).

US '947 and US '257 do not teach the particular structure of the patch as having a rate controlling membrane, nor the combination of drug with the antagonist and the siliconized release liner. It is within the skill in the art, as it is widely used, to have a rate controlling membrane and a siliconized release liner in the transdermal therapeutic patch. It is well known in the art to treat addiction or drug dependency by administering the drug and its antagonist.

US '759 is teaching the transdermal drug delivery of nicotine and mecamylamine combined in a single dose in the form of a patch. The patch comprises an impermeable backing; reservoir containing silicone polymer matrix and the drugs; and releasable liner. The patch provides a steady rate of delivery of 1-4 mg per hour of nicotine and 0.5-1 mg per hour of mecamylamine. See the abstract; col.3, lines 26-30; col.4, col.5, lines 6-9; col.6, lines 50-64; col.8, lines 6-8, 29-32, 43-50, 65-67; col.9, lines 19-41.

US '257 teaches a therapeutic system for smoking cessation comprising an occlusive backing, a nicotine containing layer, a rate controlling layer, and silicone coated release liner (abstract, col.5, lines 14-30; col.10, lines 63-64).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal patch comprising a backing, silicone adhesive layer containing the drug, rate-controlling layer, and release liner, with reasonable expectation of success of the obtained patch in treating nicotine dependency by delivering nicotine and mecamylamine. Motivation would arise from the teaching of US '759 that the administration of the drug and its antagonist together in the same patch will not allow the drug user or abuser to separate the desired portion of the composition, i.e. the drug, from the antagonist (col.6, lines 57-63).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600